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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,254	10/14/2003	Nathalie Jongen	01-1400	4012

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
08/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,254	JONGEN ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/01/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks and amended claims filed on 05/01/08 is acknowledged.

Claims 1-10 remain cancelled, claim 11 has been amended. Accordingly claims **11-12** are pending in the prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO02/089942 A1(herein onwards ('942).

('942) discloses a process of making an inhalable medicament as follows: Small crystals are made by mixing a solution of a desired substance with an anti-solvent in a fluidic vortex mixer in which the residence time is less than 1 s, for example 10 ms. The liquid within the fluidic vortex mixer (12) is subjected to high intensity ultrasound from a

transducer (20, 22) in or on the wall of the mixer, or coupled to a pipe supplying liquid to the mixer. The solution very rapidly becomes supersaturated, and the ultrasound can induce a very large number of nuclei for crystal growth. Small crystals, for example less than 5 micro meters are formed that may be of a suitable size for use in inhalers (abstract and the picture as shown on front page. ('942) further discloses that crystallization apparatus of the invention may be suitable for use in crystallizing a wide variety of different compounds. Some materials for which the crystallization procedure and apparatus would be useful, in order to provide a narrow particle size distribution and so to help control bio-availability, are: analgesics such as codeine; anti-allergens such as sodium cromoglycate; antibiotics such as penicillin, cephalosporins, streptomycins, or 15 sulphonamides; antihistamines; anti-inflammatories (page 12, lines, 6-15). A tubular apparatus is depicted on pages ¼ through ¾, fig. 1.and 8.
It would have been obvious to one of ordinary skilled in the art at the time the invention was made to prepare the inhalable claimed drugs since the art teaches preparing medicaments less than 5 micrometer diameter and that crystallization apparatus of the invention may be suitable for use in crystallizing a wide variety of different compounds. A skilled artisan would have been motivated to prepare an inhalable medicament with an aerodynamic diameter of less than 20 or 5 micrometer with a reasonable expectation of success.

Response to Arguments

4. Applicant's arguments filed 05/01/08 have been fully considered but they are not persuasive.

Applicant argues that the '942 reference does not teach or suggest the claimed species. The fact that a claimed genus or species is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness. *In re Baird,* 16 F.3d 380, 382 (Fed. Cir. 1994). The '942 reference discloses the genus of a number of pharmaceuticals directed to the treatment of several conditions/diseases. The '942 reference also discloses some species of each genus, however, it does not provide any guidance or motivation to select the claimed species of rejected claim 11 from the multitude of possible species that are encompassed by each genus of the '942 reference (page 12, lines 6-25). Therefore, claim 11 is not obvious over the '942 reference and is thus allowable.

Applicants arguments are not persuasive since the prior art provides the guidance as how to produce a medicament with the claimed diameter. The fact that the claimed species is not specifically described is not persuasive since the production of the claimed medicament with specific parameters have been discussed in the prior art. Based on the teachings and guidance provided by the prior art, one of ordinary skilled would have made any of the claimed medicament with a reasonable expectation of success. It should be noted that the rejection is not of anticipation rather it is obviousness rejection.

5. Claims 11-12 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Batycky et al. (US 2003/0180283 A1).

Batycky discloses method and apparatus for producing dry particles. The reference discloses that dry powder compositions are for pulmonary drug delivery. The dry particles of the prior art correlates with the enhanced delivery to the pulmonary system. Batycky further discloses that the aerodynamic diameter that is between about 1 and 3 microns is well suited for delivery to the alveoli or deep lung (see paragraph [0007]) on page 1). On paragraph [0046], Batycky et al. further describe the preferred dry particles are directed to inhalable salmeterol and Ipratropium compositions. (incorporated by reference see page 3.). It would have been obvious to one of ordinary skilled in the art at the time the invention was made to prepare the inhalable claimed drugs since the art teaches preparing medicaments less than 5 micrometer diameter and that crystallization apparatus of the invention may be suitable for use in crystallizing a wide variety of different compounds. A skilled artisan would have been motivated to prepare an inhalable medicament with an aerodynamic diameter of less than 20 or 5 micrometer with a reasonable expectation of success.

Response to Arguments

6. Applicant's arguments with respect to claims 11 and 12 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612